DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0525]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by [*insert date 30 days after date of publication in the* **Federal Register**].

ADDRESSES: OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Reports of Corrections and Removals—21 CFR Part 806 (OMB Control Number 0910–0359)—Extension

The collection of information required under the reports of corrections and removals, part 806 (21 CFR part 806), implements section 519(f) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360i(f)), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA) (21 U.S.C. 301) (Public Law 105–115).

Each device manufacturer or importer under § 806.10 shall submit a written report to FDA of any action initiated to correct or remove a device to reduce a risk to health posed by the device, or to remedy a violation of the act caused by the device which may present a risk to health, within 10 working days of initiating such correction or removal.

Each device manufacturer or importer of a device who initiates a correction or removal of a device that is not required to be reported to FDA under § 806.20 shall keep a record of such correction or removal.

The information collected in the reports of corrections and removals will be used by FDA to identify marketed devices that have serious problems and to ensure that defective devices are removed from the market. This will assure that FDA has current and complete information regarding these corrections and removals and to determine whether recall action is adequate.

In the **Federal Register** of December 14, 2004 (69 FR 74527), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

Respondents to this collection of information are manufacturers and importers of medical devices.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours
806.10	482	1	482	10	4,820
Totals					4,820

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

TABLE 2.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of Record-keepers	Annual Frequency per Record	Total Annual Records	Hours per Recordkeeper	Total Hours
806.20	143	1	143	10	1,430
Totals					1,430

[1]There are no capital costs or operating and maintenance costs associated with this collection of information.

In 2001, when preparing the earlier package for approval of the information collection requirements in part 806, FDA reviewed the reports of corrections and removals submitted in the previous 3 years under part 7 (21 CFR part 7) (the agency's recall provisions). FDA has determined that estimates of the reporting burden in §§ 806.10 and 806.20 should be revised to reflect a reduction of 29 percent for reports and records submitted under part 7 due

to a decrease in recall actions. The time needed to collect information has been reduced by 4 hours per record due to the implementation of a computerized program for information collection requirements in part 806.

Dated: 2-25-05
February 25, 2005.

Jeffrey Shuren,
Assistant Commissioner for Policy.

[FR Doc. 05–????? Filed ??–??–05; 8:45 am]

BILLING CODE 4160–01–S